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Drug Firms, Stymied in the Lab, Become Marketing Machines

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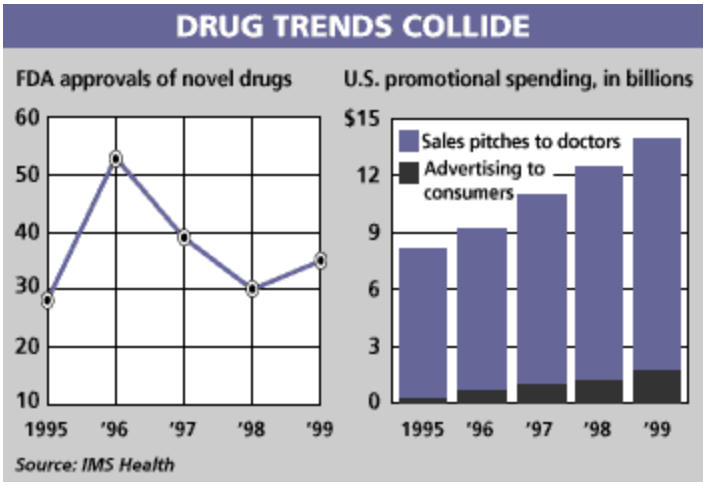
Pharmaceutical researchers have never had it so good. Their labs are stuffed with high-tech equipment. A golden age of biology has brought an avalanche of discoveries. And fat profits have bankrolled large staffs and high salaries.

The hard truth, however, is that the pharmaceutical industry's researchers are not delivering on all this promise. Their production of breakthrough medicines, the products vital to propelling revenues and profits over the next decade, has actually declined since 1996. As a result, the industry is sliding toward a crisis in which business necessities and political realities collide.

"We don't have enough in our collective pipelines," says Jean-Pierre Garnier, who will be chief executive of the combined **Glaxo Wellcome** PLC and **SmithKline Beecham** PLC.



Simply accepting lower profits isn't an option for pharmaceutical executives, since doing so could bomb their share prices and make them vulnerable to takeover. So executives, in some cases dissatisfied with the output of their own labs, are farming out much of their research to biotech companies. And they are investing more and more in marketing to boost the sales of the drugs they do manage to create. If the difficulty in producing enough new products continues -- and signs are it will -- the industry will become increasingly reliant on costly marketing schemes, and relatively less on its research operations.

Story Line

In fact, the pharmaceutical industry is gradually shifting the core of its business away from the unpredictable and increasingly expensive task of creating drugs and toward the steadier business of marketing them.

It's a transformation straight out of the movies. Hollywood studios once made all of their own movies. But as costs soared and success became trickier, the studios started to farm out much of their movie-making operations to independent production companies as a way of increasing the chances of success and sharing the costs of failure. Once seen as playing only a supporting role, marketing and distribution are now the studios' stars.

While the marketing model may work well for the studios, it is risky for the pharmaceutical industry because of a fundamental contradiction. The more marketing succeeds in convincing consumers they need a company's drugs, the less the consumers -- unhappy with how much drug makers charge -- want to see the drug makers spending their money on advertising. So drug makers' solutions to their lab woes -- raising prices and aggressively marketing -- may make good business sense for individual companies, but they are politically perilous for the industry as a whole.

Backlash

The industry's political fortunes decline steadily as it squanders some of the good will it has generated curing ills. Price controls, an idea once dismissed out of hand, are getting increasing political attention. So are proposals to allow drug re-importation from Canada and elsewhere where prices of American-made drugs are often half those in the U.S.

Maine passed a law earlier this year that allows the state government to negotiate drug prices and later set prices if negotiations fail. Congress and many state legislatures are considering similar measures. If many succeed, the industry's profits would tank. Chellie Pingree, Maine's senate majority leader and a sponsor of the price-control initiative, held up drug ads at public hearings to whip up the crowds' fury.

The ads "make people really mad," says Sen. Pingree, a Democrat. "People want [drug companies] to spend less money on that and to make sure drugs are affordable." Drug prices, especially as compared with prices charged in Europe and Canada, are expected to be a major national political issue this year. In campaign speeches this week, Vice President Al Gore is bashing the industry for "gouging the consumer unfairly." Democrats and Republicans are fighting over proposals to provide a Medicare drug benefit for many of the nation's elderly who currently must shoulder the bulk of their prescription medicine bills themselves.

Marketing Costs

The industry's response to rising complaints over prices is to repeat an argument it has used for years: Drugs are priced to support expensive and risky research. Indeed, the pharmaceutical industry's spending on research and development has tripled since 1990 to $26.4 billion. As a percentage of sales, it spends more on research than almost any other industry.

But the drug industry still spends far more on salesmen than it does on scientists. Its army of nearly 70,000 U.S. salespeople costs roughly $7 billion a year. And although they often deliver information doctors need, they do so at a high cost: The average sales call lasts seven minutes but costs companies $100 to $300 each

to make. Overall, the industry's marketing and administration expenses are generally more than twice those of research and development. At **Pfizer**, for instance, marketing and administration make up 39% of expenses, compared with 17% for R&D.

One of the fastest-growing costs at pharmaceutical companies is consumer ads. In 1998, according to the research firm Competitive Media, **Schering-Plough** Corp. spent $136 million advertising just one medicine, its allergy drug Claritin. That's more than **Coca-Cola** Co. spent advertising Coke, or **Anheuser-Busch** Cos. spent advertising Budweiser. Schering-Plough spent an additional $53 million that year on salesmen who visited doctors in person to pitch the drug, according to the research firm IMS Health.

With more and more of the industry's research being conducted in biotech labs, its core competency increasingly is marketing, not discovery. Some pharmaceutical executives find these trends disturbing. "It's the equivalent of the arms race," says Dr. Garnier. "We could have a much more efficient system to promote the drugs, but you'd get blown out of the water. You can't be rational in this effort."

The number of novel drugs approved by the U.S. Food and Drug Administration peaked in 1996 at 53. There were just 35 in 1999, and 16 through the first half of this year. While those numbers remain higher than the average of 22 drugs launched annually in the 1980s, the industry is now much bigger, so it takes more new drugs to keep up the same percentage growth.

In fact, double-digit profit growth has become the norm in the industry, which is among the most profitable. Valuations of drug stocks are above average because investors expect this to continue. Should overall industry profit growth slip, drug stocks would start carrying lower price-earnings multiples.

But "we are well past the low-hanging fruit" of drug discovery, says Fred Hassan, chairman of **Pharmacia** Corp. in comments echoed around the industry. "It's becoming very difficult to get easy wins."

The research shortfall means that the cost of producing each new drug continues to rise. The industry now estimates that each approved drug must return between $300 million and $600 million, to cover the research expense of the many that don't pan out. Meanwhile, contract research organizations, companies that perform human testing for pharmaceutical companies, have been in a funk for about a year because of the low number of new drugs coming out of industry labs.

In this situation, the industry is pinning its growth hopes less on new products and more on persuading people, including healthy ones, to buy the pills already being sold.

Consider Viagra. Though its sales rose above $1 billion last year, they were well below some projections. Now **Pfizer** Inc., which initially insisted Viagra was only for "erectile dysfunction" and not for healthy men looking for a good time, is running ads featuring smiling young couples. One ad in February called Viagra "an official sponsor of Valentine's Day." A Pfizer spokesman says the ads are intended to communicate that sexual dysfunction sometimes afflicts younger men, not that Viagra enhances normal function. The new ads, however, don't talk about erectile dysfunction. Viagra's sales continue to grow steadily.

To no one's surprise, marketing works -- sometimes better than science. There is no evidence, for instance, that Claritin functions better than competing nonsedating antihistamines like Allegra. But its ads have made it the dominant allergy drug, with $1.7 billion in U.S. sales, more than triple Allegra's. Claritin's success has been a revelation to industry executives: Buy ads, watch sales soar.

Since 1993, when television advertising of prescription drugs became common in the U.S., sales of them have doubled, to $101 billion in 1999. The share of U.S. health-care dollars devoted to drugs rose to 11% in 1998 (the latest figures available) from 8% in 1993.

The industry is launching an increasing number of "lifestyle" drugs -- such as **Merck**'s baldness remedy and **Bristol-Myers**'s drug to eliminate women's facial hair -- whose sales largely depend on inducing consumers to ask doctors for them. The best way to do that: consumer ads.

Joining Forces

Marketing isn't the industry's only answer to its research woes. Another is mergers. "One reason the industry is having consolidation is because the industry's ability to come up with research flow is not keeping with the attrition for products going off patent," says Mr. Hassan of Pharmacia, which itself is the product of a recent merger (Pharmacia & Upjohn with Monsanto).

Filling the product pipeline was a key reason behind the soon-to-close melding of Glaxo with SmithKline, Dr. Garnier says. And while Pfizer says it launched its hostile takeover of **Warner-Lambert** out of "strength," analysts figure Pfizer was pushed to make the play by the limited number of major new products in its pipeline.

But like the move toward marketing, mergers have shortcomings. They help profits for a few years as redundant support operations are cut, but they do nothing for research productivity, say academics and consultants to the industry. In fact, many believe mergers are distracting and hinder researchers' creativity. The need for double-digit growth continues, but now on a bigger sales and earnings base.

"There are all sorts of formulas out there saying that these firms will need to put out at least three or four new chemical entities per year [to sustain growth rates] and there's no firm right now doing anything more than one per year," says Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development. "It's a very tenuous time for the pharmaceutical industry."

Pressure for More

Take Pfizer. After absorbing Warner-Lambert, Pfizer will have revenue this year of roughly $31 billion and a research budget of about $4.7 billion. Hollowing out Warner-Lambert's executive ranks and paring other costs may maintain profit growth for a couple of years, but eventually, sales growth will have to carry the load. To continue growing at double-digit levels, the company by 2003 will need to be launching at least three or four drugs a year that can do $1 billion in annual sales. By 2007, when some of Pfizer's key patents expire, the company will need to launch five or six huge-selling new drugs each year.

Pfizer's own labs have come up with just seven drugs in the past 10 years, and licensed four. Warner-Lambert's labs came up with six drugs in that time and licensed a seventh -- one of which was withdrawn and three of which have low sales. Together, the two companies' labs produced fewer than two new drugs a year, not nearly enough for future growth. To create a 10% compounded annual return on its $4.7 billion research and development investment, Pfizer researchers will have to come up with products in 10 years that create $12 billion in new revenue that tenth year.

A Pfizer spokesman says the company "is very optimistic about the future" and relies not only on launching

new medicines but increasing the sales of old ones. While that can be done by testing new uses to old drugs and combining them with other drugs, the best means is boosting marketing budgets.

High Hopes

Many drug executives thought productivity would be climbing by now because of investments made five years ago in robotic drug-screening equipment. The robots speed 20-fold the process of coming up with a compound that performs a needed biological activity. "We can screen our entire chemical-compound library against a target in two to three weeks," says Edward Scolnick, president of Merck Research Laboratories. "That would have taken us years before."

What hasn't improved much is the time needed to formulate compounds into drugs the body will be able to absorb and use and that aren't toxic. Far from becoming more efficient, this process is only getting harder. Part of the reason is that as the number of marketed drugs rises, coming up with drugs that don't interact with those medicines patients are already taking is an increasingly difficult chore. More and more promising compounds are failing in the lab because of such drug-to-drug interactions.

Sometimes, toxicity problems aren't spotted until after a drug goes on the market. The list of medicines withdrawn recently because of bad side effects includes Propulsid for heartburn, Rezulin for diabetes and Duract for pain.

Some company researchers are hoping the sequencing of the human genome will lead to rapid enough discoveries to bail them out. Most experts in genomics, however, say that significant gene-based drug discoveries are at least five years away.

Prodded Into Alliances

The increasing inefficiency of research has led drug executives, just like movie executives before them, to pour money into buying and teaming up with independent production companies. Among the big biotechs that have been purchased in whole or in part: **Genentech** Inc., Agouron Pharmaceuticals, **Immunex** Corp. and **Chiron** Corp. Commitments to research alliances hit $5.3 billion in 1999, triple the 1994 level, according to Recombinant Capital, a biotech analysis firm.

The proportion of Bristol-Myers's research budget that is spent on research alliances with biotechs is up to almost 30%, and "I see that eventually going to maybe 50%," says Peter Ringrose, research chief. At Warner-Lambert, money spent on alliance research rose from nothing five years ago to 25% of the budget last year.

The subtext for these deals: Concern that small biotechs' labs may be better at discovering drugs than the giants'. While little data support this notion so far, a Tufts University study found that the number of drugs approved by the FDA that were discovered by the firm asking for the approval fell to 61% in the mid-1990s from 72% in the mid-1960s. The growing biotech alliances suggest that the number is even lower now.

Some think the biotech firms are just hungrier. "If you drive around the Bay Area labs [of biotech companies] at 2 a.m., all the lights are still on," says Joe Zammit-Lucia, president of Cambridge Pharma Consultancy.

But as more pharmaceutical giants look to the biotechs for innovative compounds, their prices rise. "I used to

go to biotech companies all the time, and we were the only ones," says Dr. Garnier. "Lately, everybody is looking at the same assets."

In addition, with their share prices improved and their financial strains lessened, biotechs are increasingly reluctant to license away their best potential drugs to their bigger brethren. "There are a growing number of biotechs that have the skills and the desire to bring products to market directly" by using contract testing, manufacturing and sales companies, says William Haseltine, chief executive of **Human Genome Sciences** Inc. "We are not a service industry … for Big Pharma."

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